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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/691,854	10/23/2003	Mark H. Falahee	FLH-10702/29	6727

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EXAMINER

PREBILIC, PAUL B

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 03/10/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/691,854	Applicant(s) FALAHEE, MARK H.	
	Examiner Paul B. Prebilio	Art Unit 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 February 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 October 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Drawings

The drawings are objected to because (1) it is not clear what is to the left of Figure 7A and projection lines are missing in Figures 9A, 9b, and possibly Figure 7A. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

The disclosure is objected to because of the following informalities:

There is no brief description of Figure 4F on page 2 of the specification.

Appropriate correction is required.

Claim Objections

Claim 3 is objected to because of the following informalities:

The claim language is grammatically awkward. It would be clearer to replace the language after "wherein" with ---the radiolucent material contains carbon fiber---

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4 and 7-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 4, it is unclear what element has a radiopaque marker on it.

Regarding claim 7, it is not clear how a trapezoid can be formed from only three walls because a trapezoid is a four-sided polygon. In addition, the use of "one or more jigs" does not make sense in view of the present invention as disclosed because only one jig was described in the rest of the specification.

Regarding claim 8, "the trapezoid" lacks antecedent basis. Also, the claim language of singular "trapezoid" does not make sense based upon the end of the claim that appears to require more than one trapezoid.

Regarding claim 9, since a jig is not normally part of an implant, the preamble is not considered to be consistent with the scope of the claim body. Alternatively, it is not

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clear whether the jig is meant to be positively or inferentially recited; see MPEP

2173.05(e), which is incorporated herein by reference.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-5, 7, and 8 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4, 6, and 8-10 of copending Application No. 10/462,498. Although the conflicting claims are not identical, they are not patentably distinct from each other because the present claims are so similar to the copending claims that they can be read on them. For this reason, the Examiner asserts that the present claims are clearly obvious over the claims of the copending application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim 6 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of copending

Application No. 10/989,021. Although the conflicting claims are not identical, they are not patentably distinct from each other because the present claim 6 can be read on by copending claim 1 such that claim 6 is considered to be clearly obvious in view thereof.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 7, and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Michelson (US 6,302,914). Michelson anticipates the claim language where the sidewalls as claimed are met by elements (112,114) of Michelson, the backwall as claimed is met by trailing end (130), and the gate as claimed is door (134) of the open front (120); see Figures 1 to 7, and column 5, line 65 to column 6, line 65.

Claims 1, 6, and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Li et al (US 6,039,761). Li anticipates the claim language where the sidewalls as claimed are walls (64) of Li, the backwall as claimed is wall (54), the gate as claimed is flap seal (70) and the opening as claimed is passageway (63); see Figures 1, 2, 3, 45, and 46, column 7, line 35 to column 8, line 35, column 9, lines 14-67 and column 14, lines 27-39.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 5 is rejected under 35 U.S.C. 102(b) as anticipated by Li et al (US 6,039,761) or, in the alternative, under 35 U.S.C. 103(a) as obvious over Li et al (US 6,036,761) in view of Stubstad (US 3,867,728).

Li anticipates the claim language as explained *supra* where the indentation is shown in Figure 46 along the backwall.

Alternatively, one may not consider the indentation of Li to be able to limit neurocompression as claimed. However, Stubstad teaches that it was known to indent backwalls of similar implants in order to limit the pressure on adjacent nerves; see column 3, lines 29-63. Therefore, it is the Examiner's position that it would have been obvious to shape the back wall of Li to prevent neurocompression, by making the indentation larger, in order to make the patient more comfortable, as implicitly taught by Stubstad.

Claim 8 is rejected under 35 U.S.C. 102(b) as anticipated by Li et al (US 6,039,761) or, in the alternative, under 35 U.S.C. 103(a) as obvious over Li et al (US 6,039,761) in view of Ralph et al (US 6,447,548). Li et al is interpreted as meeting the claim language where only one trapezoid implant is required; see *supra*.

Alternatively, one could interpret the claim language as requiring multiple trapezoidal implants, which is not taught by Li. However, Ralph teaches that it was known to have a plurality of different sized implants for different parts of the spine in order to adequately treat a spinal malady; see the front page of the patent. Therefore, it is the Examiner's position that it would have been prima facie obvious to make a plurality of different sized implants for the Li invention for the same reasons that Ralph does the same.

Claim 9 is rejected under 35 U.S.C. 102(b) as anticipated by Li et al (US 6,039,761) or, in the alternative, under 35 U.S.C. 103(a) as obvious over Li et al (US 6,039,761) in view of Carl et al (US 6,607,530). Li anticipates the claim language when one does not interpret the claim language requiring a jig.

Alternatively, if one does consider a jig positively required, Li does not fully meet the claim language. However, Carl teaches that it was known to use jigs, screws, and screw holes in similar implant in order to fix similar implants to the body; see Figures 1A to 2A and column 6, lines 54-67. Therefore, it is the Examiner's position that it would have been considered prima facie obvious to use a jig, screws, and screw holes in the implant with Li as a means to fixate it to adjacent vertebrae.

Claims 2-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Li et al (US 6,039,761) in view of Chung et al (US 6,712,852). Li fails to disclose materials to make the implant. However, Chung teaches that it was known to make similar spinal implants of carbon fiber reinforced material and to mark such implants with radiopaque markers; see column 6, lines 34-51 and column 8, lines 13-20. Therefore, it is the

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Examiner's position that it would have been obvious to make the implant of Li out of carbon fiber reinforced radiolucent material and to mark it with radiopaque markers for the same reasons that Chung does the same.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 USC 102 or 35 USC 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is respectfully requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is respectfully requested in response to this Office action if the application is not stored in image format (i.e. the IFW system) or published.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Paul B. Preblich whose telephone number is (571) 272-4758. He can normally be reached on 6:30-5:00 M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, McDermott Corrine can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for

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published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Paul Prebilit
Primary Examiner
Art Unit 3738